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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/511,939	02/24/2000	Ian Tomlinson	3789/86470	5170

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EXAMINER

PONNALURI, PADMASHRI

ART UNIT PAPER NUMBER


1639

DATE MAILED: 07/11/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/511,939	Applicant(s) Tomlinson et al	
Examiner Padmashri Ponnaluri	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 21, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-52 is/are pending in the application.
- 4a) Of the above, claim(s) 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 6) ☐ Other:

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DETAILED ACTION

1. Applicant's election of 'protein L' as generic ligand, 'VI' as binding polypeptide, and 'hen egg lysozyme' as in Paper No. 20, filed on 4/21/03 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicants have submitted that there are no two generic ligands or generic ligand binding sites, thus the election of 'protein L' as the generic ligand has been considered as first generic ligand and second generic ligand.

2. Claims 32-52 are currently pending in this application.

3. Claim 32 is withdrawn from further consideration pursuant to 37 CAR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 9.

4. Claims 33-52 are currently being examined in this application.

5. The disclosure is objected to because of the following informalities:

the specification does not have a clear copy, i.e., some of the text is either missing or not clearly visible (see pages 10, 12, 20, 22, 30, 32, 34, 42, 44 and 46). Applicants are requested to file a substituted specification.

Appropriate correction is required.

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6. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Applicant is invited to notice that boxes 6, 10, 11 and 12 were checked by the draftsman. If applicant intends to renumber the informal figures, applicant is encouraged to amend the specification so that the description of the renumbered figures corresponds to the renumbered figures.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 33-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 is vague and indefinite by reciting 'a method for selecting a binding polypeptide from a repertoire of polypeptides..... comprising the steps of a) contacting the repertoire with the generic ligand to select polypeptides bound thereto....., b) contacting the selected pool of polypeptides with target ligand to select a population of polypeptides which bind to the target ligand.' in the claimed method it is not clear whether the first selected pool of binding polypeptides are still bound to the generic ligand such that the target ligand binds to a different binding site. That is it is not clear whether the target binding site and ligand binding site are different from each other. Applicants are requested to clarify.

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In claim 33, step b) applicants are requested to amend 'first selected pool of polypeptides' to **'first selected pool of binding polypeptides'**.

In claims 33 and 52 the amendment to the claims to add 'comma' after first and second seems to be grammatical error. Applicants are suggested to correct the error.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

10. Claims 33-41, 44-52 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,057,098 (Buechler et al).

The instant claims briefly recite a method for selecting binding polypeptide from a repertoire of polypeptides, said binding polypeptide comprise a first target ligand binding site and

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a second generic ligand binding site, the method comprising: a) contacting the repertoire with the generic ligand; selecting the binding polypeptides bound to the generic ligand; b) contacting the selected binding polypeptides with the target ligand; and selecting the binding polypeptides which bound to the target ligand.

Buechler et al teach methods of producing a multivalent polypeptide display library. The reference teaches that a library of phage (refers to instant claim 40) displaying fusion proteins (repertoire of polypeptides of the instant claims) comprising polypeptides to be screened and a tag. The reference teaches that the polypeptides among the members of the library differ (refers to the instant claims 44-51). The tag can be any polypeptide with a known receptor showing high binding specificity for the tag (see column 7, lines 10-11). The library is contacted with a receptor (refers to the generic ligand of the instant claims) having a specific affinity for the tag (refers to first binding site or generic ligand binding site of the instant claims). The library members bound to the receptor are then separated from the unbound library members to produce a sublibrary of polypeptides (refers to first selected pool of binding polypeptides of the instant claims) (see i.e., column 2, lines 20-35). The selected sublibrary of polypeptides are screened by contacting the library with a target (refers to the target polypeptide of the instant claims), and separating the library members bound to the target via their displayed polypeptides. The reference teaches that the polypeptides of particular interest are antibodies or fragments thereof (refers to instant claims 36-39)). The reference teaches that a second cycle of polyvalent enrichment is performed, followed by a second cycle of affinity enrichment to the screening target (i.e., see column 14, lines

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34-36). The reference teaches that for the Fab libraries, two similar rounds of selection can be performed, with the products of one round becoming the starting materials of the second round, and the first round of selection is performed with a receptor to the first tag, and the second round with a receptor to the second tag (refers to claims 52 of the instant claims). The reference in example 13 teaches that the phage library was contacted with CKMB (target), and the bound phage is contacted with NiNTA (generic ligand), and the bound phage is subjected to further panning with CKMB (see example 13, columns 28-29). The reference teaches the instant claims 45-46, 50-51 limitations (i.e., see column 18, characteristics of libraries) and also the limitations (i.e., "... variation is achieved by ..") are considered as product by process limitations. The reference clearly anticipates the claimed invention.

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 U. S. P. Q. 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 U. S. P. Q. 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 U. S. P. Q. 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 U. S. P. Q. 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CAR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CAR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CAR 3.73(b).

12. Claims 33-52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2, 5-14, 36-44 of

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copending Application No. 09/192,854. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claimed method for selecting a population of binding peptides which bind a target ligand in a first binding site and a generic ligand in a second binding site is obvious over the reference claimed method, because the binding peptides of the instant claims read on the functional peptides of the '854 application, and the method steps are the same..

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Ponnaluri whose telephone number is (703) 305-3884. The examiner is on ***Increased Flex Schedule*** and can normally be reached on Monday to Friday from 7.00 AM to 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

P. Ponnaluri
Primary Examiner
Technology Center 1600
Art Unit 1639
10 July 2003


PADMASHIRI PONNALURI
PRIMARY EXAMINER